

Claims

- [1] An enteric, sustained-release tablet comprising paroxetine in which a separation layer is introduced between a sustained-release tablet core comprising paroxetine as pharmaceutically active substance and an enteric coating layer enclosing the tablet core in order to maintain the drug release behavior without regard to the residence time of the drug in an acidic environment, wherein the separation layer is prepared from a mixture of a) at least one water-insoluble polymer selected from the group consisting of ethylcellulose, polyvinylacetate and ammoniomethacrylate copolymer type B and b) at least one water-soluble polymer selected from the group consisting of hydroxypropylmethylcellulose, methylcellulose, polyvinylpyrrolidone, hydroxypropylcellulose, ammoniomethacrylate copolymer type A and polyvinylalcohol and completely encloses the tablet core.
- [2] An enteric, sustained-release tablet comprising paroxetine in which a separation layer is introduced between a sustained-release tablet core comprising paroxetine as pharmaceutically active substance and an enteric coating layer enclosing the tablet core in order to maintain the drug release behavior without regard to the residence time of the drug in an acidic environment, wherein the separation layer is prepared from a water-soluble polymer selected from the group consisting of hydroxypropylmethylcellulose, methylcellulose, polyvinylpyrrolidone, hydroxypropylcellulose, ammoniomethacrylate copolymer type A and polyvinylalcohol and completely encloses the tablet core.
- [3] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 1 or Claim 2, wherein the paroxetine is paroxetine hydrochloride hemihydrate.
- [4] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 1 or Claim 2, wherein the separation layer is comprised within from 1 to 30 w/w% based on the weight of the tablet core.
- [5] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 1 or Claim 2, wherein the tablet core is prepared by further adding low-viscosity hydroxypropylmethylcellulose to granules comprising paroxetine and high-viscosity and low-viscosity hydroxypropylmethylcellulose.
- [6] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 5, wherein the high-viscosity hydroxypropylmethylcellulose has a viscosity ranging from 3,000 to 14,000 cps and the low-viscosity hydroxypropylmethylcellulose has a viscosity ranging from 40 to 60 cps.
- [7] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 5, wherein the paroxetine-containing granules are comprised in the tablet core within from 40 to 90 w/w% based on the total weight of the tablet core.

- [8] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 5, wherein the paroxetine-containing granules comprise 3 to 30 w/w% of high-viscosity hydroxypropylmethylcellulose and 10 to 40w/w% of low-viscosity hydroxypropylmethylcellulose.
- [9] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 1, wherein the enteric coating layer is prepared from a material selected from the group consisting of methacrylate copolymer, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate and carboxymethylethylcellulose.
- [10] The enteric, sustained-release tablet comprising paroxetine as set forth in Claim 5, which further comprises pharmaceutically acceptable excipients, binders, lubricants, disintegrants, etc. in the tablet core.